

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Jim Heslin on 10/6/2011.

The application has been amended as follows:

Claim 11, line 1 delete "selective" and insert --selectively--.

Allowable Subject Matter

Claims 1-13 allowed.

This application is in condition for allowance except for the presence of claims 14-22 directed to an invention non-elected without traverse. Accordingly, claims 14-22 have been cancelled.

The following is an examiner's statement of reasons for allowance: While the induction of therapeutic hypothermia via inhalation is known in the art, the typical coolant phases in the art at the time of invention were either gas (Ferrigno (US 6,303,156 B1)), gas with liquid particulates (Kumar *et al.* (US 2003/0131844 A1; hereinafter "Kumar"); Jiang *et al.* (US 2003/0136402 A1 and US 2005/0042170 A1; hereinafter "Jiang I" and "Jiang II", respectively)), liquid (Kasza (US 6,244,052 B1; hereinafter "Kasza")), or liquid with frozen particulates (Kasza). Before Applicant's

priority date of 1/22/2004, the prior art taught away from gas with frozen particulates as a coolant phase for inducing therapeutic hypothermia, as detailed below:

1. Kumar, para [0055], "However, since water turns to ice at 0 °C, cooling below this temperature may result in formation of ice crystals within the cells of the respiratory system. Ice crystals may disrupt cellular function and lead to organ failure and death. Applicants prefer and recommend maintaining the temperature of the inspired gas at no less than 1-4 °C."

2. Jiang I, para [0023], "Mists may be administered at...*near-freezing* temperatures." (emphasis added)

3. Jiang II, para [0076], "In order to prevent liquid from freezing at the orifices and *to control the temperature of the mist generated*, the orifice walls are heating elements that maintain a desired temperature, *i.e. 1 °C*." (emphasis added)

Indeed, even conventional wisdom, as reported by the New York Times on Jan. 12, 1910, taught that "inhaling fog which has frozen into minute particles of ice...develops a form of pneumonia which is usually fatal." Moreover, though pharmaceutical agents in frozen particulate form capable of pulmonary delivery were known at the time of invention (Kipp *et al.* US 2003/007329 A1; abstract), such preparations were not disclosed as being generated in combination with a system comprising a breathing interface (i.e. were not disclosed as being prepared on-site); instead, they were described as being pre-prepared and stored prior to treatment. Indeed, the reason for their frozen state was not to affect a patient's body temperature

but to enhance stability for long-term storage, and there is no teaching that the delivery of such particles would be capable of inducing hypothermia.

It was not until **after** Applicant's priority date of 1/22/2004 that the inhaling of frozen particles generated in the context of a ventilation machine, particularly for the induction of therapeutic hypothermia, was described by others in the art, including Jiang *et al.* (WO 2005/113046 A2) and Akselband *et al.* (US 2005/0279108 A1; para [0020]). Therefore, Applicant's invention of an apparatus comprising a source of breathing gas, a heat exchanger, an ice particle generator configured to introduce fine ice particles into the flow of breathing gas and a breathing interface configured to deliver the flow of breathing gas containing the fine ice particles to the patient was not known nor fairly taught in the art prior to Applicant's disclosure.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHRYN D. SHEIKH whose telephone number is (571)270-5178. The examiner can normally be reached on Monday-Friday 8:30am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LoAn Thanh can be reached on (571)272-4966. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. S./
Examiner, Art Unit 3764

/LoAn H. Thanh/
Supervisory Patent Examiner, Art Unit 3764